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UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT:	Coelho, Philip
SERIAL NO.:	09/672,074
FILED:	September 28, 2000
FOR:	Freezing and Thawing Bag, Mold, Apparatus and Method

ART UNIT: 1744

EXAMINER: Olsen, K.

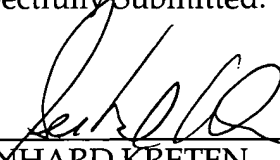
To: Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**Authorization to Charge Deposit Account**

It is believed that all fees due with respect to the filing of the appended Brief on Appeal are included herewith. However, should any additional fees now be due, it is respectfully requested that such fees be charged to deposit account 11-1734, attorney docket number 30111-pa. A duplicate copy of this authorization is enclosed.

Dated: May 23, 2003

Respectfully Submitted:

  
BERNHARD KRETEN  
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Registration No.: 27,037



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CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

**Applicant:** Coelho, Philip  
**Serial No.:** 09/672,074  
**Filed:** September 28, 2000  
**For:** Freezing and Thawing Bag, Mold, Apparatus and Method  
**Paper:**

1. Appeal Brief - responsive to the Notice of Appeal dated March 24, 2003 (original and three copies);
2. Exhibit One (Baxter Articles comprising 8 of pages)
3. Authorization to charge deposit account (original and one copy);
4. A check in the amount of \$320.00 which reflects the government fee for filing the appeal brief; and
5. Return receipt card.

I hereby certify that the above identified correspondence, which is attached, is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to:

Commissioner of Patents, P.O. Box 1450; Alexandria, VA 22313-1450

on May 23, 2003.

Rodica A. Dima

Rodica A. Dima  
(Signature)

May 23, 2003  
(Date of Signature)



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UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Coelho, Philip  
SERIAL NO.: 09/672,074  
FILED: September 28, 2000  
FOR: Freezing and Thawing Bag,  
Mold, Apparatus and Method

ART UNIT: 1744

EXAMINER: Olsen, K.

#  
16/w.m.  
6/3/03

To: Commissioner of Patents  
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Alexandria, VA 22313-1450

**BRIEF ON APPEAL**

The following is an Appeal to the Board of Appeals with respect to the final rejection by the Examiner in the above-identified case. Relief from the Examiner's final rejection is hereby respectfully requested with respect to claims 19 through 22 and 56 through 67. A Notice of Appeal was filed on March 24, 2003.

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HD:clients: Patent:ThermoGenesis:Appeal Brief/30111-pa

**REAL PARTY IN INTEREST**

The real parties in interest are the appellant named in the caption of the brief and ThermoGenesis, Corp. as assignee.

### **RELATED APPEALS AND INTERFERENCES**

There are no appeals or interferences related to this appeal.

### STATUS OF CLAIMS

This application is a divisional of US patents 6,146,124 (November 14, 2000) and 6,232,115 (May 15, 2001). This application was filed with claims 1 through 45. In a preliminary amendment filed with the application, claims 6-10, 14-18, 24-27 and 33-44 were canceled, certain claims amended and claims 46-55 added. By amendment on August 13, 2001, applicant elected claims 19-23 and added claims 56-62. By amendment on May 29, 2002, applicant cancelled claim 23, amended other claims and added claims 63-67. By amendment on March 31, 2003, applicant amended claims 63-67. In the final rejection mailed September 23, 2002, (as modified by the advisory action dated April 11, 2003): Claim 63 is rejected under 35 U.S.C. 102(b) relying on Medwed. Claims 19 through 22, 56, 57, 60, and 61 are rejected under 35 U.S.C. § 103(a) relying on Sneider in view of Heck with or without Nathoo or Medwed. Claims 19-22, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al (USP 4,943,222) or Medwed (USP 4,397,804). Claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed. Claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed. Claims 58, 59, and 62 are rejected under 35 U.S.C. § 112 second paragraph. On March 24, 2003, Appellant noted this appeal.

Claims 19 through 22 and 56 through 67 stand on appeal.

### STATUS OF AMENDMENTS

An amendment received on March 31, 2003 after final rejection has been tendered and accepted to reduce the issues on appeal, as they relate to a rejection under 35 U.S.C. 112, first paragraph for claims 63-67.

### CONCISE SUMMARY OF THE INVENTION

Preservation of blood, cellular biological substances, tissue and other thermolabile products frequently involves product maintenance at extremely cold temperatures. Cellular biological substances are the fundamental, structural and functional unit of living organisms. Thermolabile substances are those substances which are easily altered or decomposed by heat. One economical mode for containment involves the use of encapsulating plastic since plastic is relatively inexpensive and lends itself to mass production techniques. However, many plastics suffer from brittleness at extremely low cryogenic temperatures and seams are sometimes susceptible to fracture. As recently as March 2003, Baxter, a titan in the industry, has publicly announced its unsolvable problem of bag breakage. See the attached news releases (exhibit one).

In addition, bags such as Baxter's are formed either by folding over a planar material and seaming along peripheries or layering two planar materials and seaming along the peripheries; they have a generally ovoid shape when filled with a liquid. This is because the cross-sectional area adjacent either the fold or the seam has an area of decreasing cross-sectional width as it tapers from the center. While for many applications, this type of narrowing is unobjectionable, for certain biological fluids such as white stem cells, a bag having non-uniform thickness along its cross-section may impair the integrity of the biological product, particularly during temperature changes. One reason for quality loss during a change in temperature may involve the differential thermal gradient within the thermolabile or cellular substance caused by variations in thickness induced by the geometric shape of the bag itself. Stated alternatively, the center portion of the bag is thicker than the edges.

A corollary to the above-enunciated problem entails the fact that the prior art bags, with their thicker center portions, also provides a non-planar surface on opposing sides of the bag. This results in a "high spot" which also makes uniform temperature alteration of the contents difficult especially when heat exchange is attempted by contact with a substantially planar surface that provides the heat gradient. Because the bag has a high crown area, uniform contact along the entire cross-section of the surface will have been precluded.

Figure 8 reflects prior art bag structure and highlights the inherent problems associated therewith. The radio frequency seam S is thinner than the non-seamed plastic forming the bag and has its weakest point W at an edge of the seal closest to the interior I. When the product P begins to freeze, the product freezes first at the thinnest part of the bag, i.e. at edge E. Freezing proceeds inwardly, from the outside in, until an unfrozen core C exists. As the core C freezes, it expands and generates forces F which collimate and focus on the edge E because of the geometrical configuration of the bag. The force F frequently causes bag rupture at the weakest point W because the wedging force appearing at edge E tries to separate the seam with a turning moment M. Recall the bag material tends to become brittle at low temperatures, exacerbating this problem.

Figure 13 reveals a further site of prior art bag weakness. When an access port tube T is to be fitted to the bag, two horseshoe-shaped RF horns H close on the plastic membrane around the tube T and then the membrane at the seal area S. This causes another weakened area W where bag failures commonly occur.

The instant invention addresses all of the difficulties noted hereinabove. One manifestation of the problems solved includes the formation of peripheral seams circumscribing the bag which are appreciably stronger than prior art seam structures. Preferably, the bag is formed from two symmetrical sections, each vacuum formed to provide a major wall flanked by a radiused end wall section and circumscribed by a peripheral flange. It is contemplated in one form of the invention that two half portions defining a plane of symmetry are thus formed and adhered together so that the peripheral flanges are in mating registry and sealed such as by means of adhesive, ultrasonic, RF welding or other means. The increased surface area of the peripheral seam flange coupled with the radiused end wall interposed between the seam flange and the major wall of the bag dissipate forces which in prior art bags could have lent themselves to rupture at the seam area.

By vacuum forming the two halves, the contour of the side wall can be carefully controlled to make them substantially planar. Thus, when the two halves are united, a container having substantially uniform cross-section substantially along the entire extent will have been provided. This geometry encourages uniform thawing, freezing and imperviousness to the stresses that attend the seams and the radiused end wall at cryogenic temperatures. This geometry also provides space efficient storage and reduced heat invasion from a warmer ambient medium when the plurality of bags are placed with their planar surfaces in contact with each other.

## ISSUES

### Issue No. 1:

Whether claims 58, 59, and 62 should be rejected under 35 U.S.C. 112, second paragraph.

### Issue No. 2:

Whether claim 63 is unpatentable under 35 U.S.C. 102(b) as anticipated by Medwed.

### Issue No. 3:

Whether claims 19-22, 56, 57, 60, and 61 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider (USP 4,591,357) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

### Issue No. 4:

Whether claims 19-22, 56, 57, 60, and 61 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al (USP 5,108, 387) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804).

### Issue No. 5:

Whether claims 63-67 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed.

### Issue No. 6:

Whether claims 63-67 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Falk in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed.

### GROUPING OF CLAIMS

Claim 19 stands alone.

Claim 20 stands alone.

Claim 21 stands alone.

Claim 22 stands alone.

Claim 56 stands alone.

Claim 57 stands alone.

Claim 58 stands alone.

Claim 59 stands alone.

Claim 60 stands alone.

Claim 61 stands alone.

Claim 62 stands alone.

Claim 63 stands alone.

Claim 64 stands alone.

Claim 65 stands alone.

Claim 66 stands alone.

Claim 67 stands alone.

**ARGUMENT BY APPELLANT WITH RESPECT TO**  
**EACH OF THE ISSUES PRESENTED**

**ISSUE NUMBER 1:**

**Whether claims 58, 59, and 62 should be rejected under 35 U.S.C. 112, second paragraph:**

**Examiner's Position**

"The preamble of claims 19 and 60 states the invention is drawn to a method of forming a bag, but claims 58, 59, and 62 appear to be drawn to a method of using the bag making it unclear what class of statutory invention the applicant is claiming (a process of making or a process of use?)."

**Appellant's Position**

The Examiner has inadvertently touched upon the essence of the invention: a bag which, once formed, is breakage resistant, particularly when filled with a fluid and then frozen. Please recall that the Examiner mandates the different classes of invention — not applicant. Applicant should not be penalized because the invention does not fall neatly into a statutory invention class. If anything, having confounded the classification system is strong evidence of invention.

The Examiner refers to the language in claims 58, 59 and 62 that specifies freezing the bag and objects to its recitation in a claim. However, the Examiner is not bothered that claim 20 for example requires placing a substance in the bag. How is that bag "forming"? It is uncontroverted law that an applicant should be allowed to recite details that define the invention. Applicant has done so. Once the Examiner has attached patentable weight to these recitations, it is clear that the prior art is legally

20 not rejected because adding the thermally stable substance can be part of the process. (see clm. 56+57)

irrelevant. By attacking these claim recitations, the Examiner is stripping key elements away from the invention by elevating form over substance.

It is respectfully submitted that the bag formed by this method is tailored to serve well in hostile environments as claimed. Please see the preamble of claim 60 for example which specifies resistance to phase change of medical fluid. Doesn't this recitation "set the stage" for claim 62?

ISSUE NUMBER 2:

**Whether claim 63 is unpatentable under 35 U.S.C. 102(b) as anticipated by Medwed:**

**Examiner's Position**

"Medwed discloses a forming a container (i.e. bag) which comprises forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface, and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface (fig. 2 as an example). A sheet is placed over said mold and is caused to conform to the mold and retains having the configuration of the mold (fig. 1 and 4). The conformed sheet is removed from the mold and the first sheet is closed with another sheet parallel to the planar surface (fig. 1 again). It would appear that the "thermoplastic" utilized by Medwed would qualify as a "thermosetting material" giving the claim language its broadest reasonable interpretation. Moreover, the container constructed by Medwed would also read on the claim language drawn to the resistance to brittleness and deformation giving those claim terms their broadest reasonable interpretation."

### Appellant's Position

what is the  
distinction between  
a "bag" that maintains  
its shape and  
a container

Undersigned does not agree that Medwed teaches a bag. Medwed's container is not a bag. Further, inter alia Medwed is not flexible without brittleness to resistance or deformation as claimed. How can the Examiner reject claim 63 as anticipated by Medwed, yet in issues 5 and 6 believes Medwed's inclusion for claim 63 under 35 U.S.C. 103(a) is optional? How relevant can Medwed be?

how  
does  
this  
define  
over  
Medwed

With respect to rejections under 35 U.S.C. § 102, it may be beneficial to consider the following binding, compelling precedent articulated by the Court of Appeals for the Federal Circuit:

Plastic  
containers  
are inherent  
something  
what  
flexible

"... anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference." *Akzo N.V. v. United States ITC*, 808 F.2d 1471, 1 U.S.P.Q.2d 1241 (Fed. Cir. 1986).

Further, "those elements must either be inherent or disclosed expressly . . ." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987). "... and must be arranged as in the claim[s] . . ." *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 231 U.S.P.Q. 644 (Fed. Cir. 1986).

In addition, "... [the] absence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986).

The Examiner claims that the containers formed in Medwed are analogous to those formed by the instant invention. In the abstract of the patent, Medwed describes "stable containers of uniform wall thickness [that] will be produced." In the specification, he declares that an object of his invention is to produce "containers having

edge and corner portions of appropriate thickness to achieve satisfactory rigidity” (col. 1, lines 51-52).

Medwed is totally unconcerned with fracture resistant bags, but instead teaches the manufacture of containers used for packaging food (column 1, lines 9-10). Medwed does not see the structure associated with his invention as being a possible solution to improve bags to make them “flexible without brittleness or resistance to deformation”.

Moreover, the bags produced by the method of the present invention are not rigid like the containers of Medwed. The bags are molded, but retain “memory” of their shape (specification page 10, line 27 through page 11, line 2) and may be manipulated to move enclosed substances within the bag (see specification, page 10, lines 9-10). Applicant’s bags therefore are flexible and not brittle or resistant to deformation. Thus, the present invention would not be anticipated by its teachings. The rejection under 35 U.S.C. § 102 should be overturned.

isn't this true of any plastic container

ISSUE NUMBER 3:

**Whether claims 19-22, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider (USP 4,591,357) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804):**

**Examiner’s Position**

“Sneider discloses a container having a planar wall, a radiused periphery and a peripheral ledge which retains its shape (fig. 1 and 2). However, Sneider does not explicitly identify how the container is constructed. Heck teaches in an alternate medical container that medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves (col. 2, lines 29-39). Nathoo evidences that vacuum molded halves are less

susceptible to tearing (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the formation of the container of Sneider because the prior art recognized that vacuum molding is a conventional means for constructing medical containers. In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the container of Sneider as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Sneider discloses a plurality of portals (fig. 1 and 2) and the teaching of Sneider in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. The container of Sneider is disclosed as utilized for medicines requiring dilution and medicines can include thermolabile or biological substances. Portal 16 would be closed during mixing."

#### **Appellant's Position**

At the outset, undersigned respectfully submits that the Examiner's citation of references under 35 U.S.C. § 103 is confusing. If the instant invention is obvious "with or without" a particular reference, there are three possibilities: First: inclusion of the reference is superfluous and irrelevant, Second: the initial combination of references is deficient, or Third: the standard for obviousness is being ignored altogether.

"One of ordinary skill in the art" is the Examiner's avowed criterion. Sneider is concerned with a container for drug isolation and subsequent mixing. What does this

have to do with Heck's flow through chamber? What do either have to do with bag molding?

Perhaps one skilled in the art is Baxter. Their Cryocyte container can not be made without fracture and the reasons why have eluded them even though Sneider and Heck were public documents in 1986 and 1984 respectively.

If this combination of a Sneider and Heck are not obvious enough then Nathoo - if the Examiner is to be believed - resolves most residual doubt. If any doubt remains, the Examiner asserts Medwed will dispel it. Medwed was discussed supra and incorporated herein.

Nathoo teaches glass fiber and resin in a mold where fluid lubrication minimizes fiber tears. The reason the Examiner believes this patent is relevant is because it is in the appropriate searching subclass for molding methods. This is also why the Examiner did not like the claims rejected under 35 U.S.C. 112 (issue 1 supra); they do not fit neatly in the molding subclass. *What what point is here*

Perhaps that is also why Baxter can not solve the problem of breaking bags. If Baxter were looking at the same references as the Examiner could they see a solution to their problem which has plagued them such that they announced withdrawal from a market where they had enjoyed a large market share?

When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." *Interconnect Planning Corp. v. Feil*, 774 F.2d at 1143, 227 U.S.P.Q. at 551. Citing *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n. 14, 221 U.S.P.Q. 929, 933 & n. 14 (Fed. Cir. 1984).

*What does Baxter have to do with it. Sneider is not a blood bag cryocyte bag.*

"Something in the prior art as a whole must suggest the desirability and thus the obviousness of making the combination." *Lindemann Mashcinenfabrick GmbH v. American Hoist and Derrick Co.*, 780 F.2d 1452, 1462, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984).

"It is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention." *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 437 F.2d 1044 (Fed. Cir. 1988).

These precedents, which are recent decisions from the Court of Appeals for the Federal Circuit are binding precedents with respect to the manner in which patents showing the prior art can be combined. When relying on these principles, it is apparent that the prior art cannot be combined as the Examiner has proposed because there is no teaching suggesting such a combination.

It is Black Letter Law the Patent and Trademark Office's burden is to establish a prima facie case of obviousness. The Patent and Trademark Office has met its burden only when it fully describes: "1) What the reference discloses, teaches and suggests to one skilled in the art; 2) What the reference lacks in disclosing, teaching or suggesting vis-à-vis the claimed features; 3) What particular teaching or suggestion is being relied upon either via a reference itself or knowledge of person of ordinary skill in the art; 4) A statement explaining the proposed modification in order to establish the prima facie case of obviousness; and finally 5) the motivation behind the statement of obviousness which comes from three sources: a) teachings of the prior art; b) nature of the problem to be solved; or c) knowledge of persons of ordinary skill in the art", see *In re Rouffet* 47 USPQ2d 1453 (Fed. Cir. 1998).

The Examiner has failed to meet these threshold requirements to establish prima facie obviousness:

"Prior art reference, in order to be relied upon as basis for rejecting applicant's invention, must either be in field of applicant's endeavor or, if not, be reasonably pertinent to particular problem with which inventor was concerned; combination of elements from non-analogous sources, in manner that reconstructs applicant's invention only with benefit of hindsight, is insufficient to present prima facie case of obviousness." *In re Oetiker*, 24 U.S.P.Q.2d 1443. [Emphasis added.]

In the absence of such a prima facie showing, the Examiner's rejection cannot stand:

"Decision rejecting claims in utility application as obvious over combination of prior art references must be reversed, since obviousness analysis in decision is limited to discussion of ways that multiple references can be combined to read on claimed invention, but does not particularly identify any suggestion, teaching, or motivation to combine references, and does not include specific or inferential findings concerning identification of relevant art, level of ordinary skill in art, nature of problem to be solved, or any other factual findings that might support proper obviousness analysis." *In re Dembiczak*, 50 U.S.P.Q.2d 1614. [Emphasis added.]

While Sneider is directed to the medical practice, it does not contain all the claim elements of the present invention, as the Examiner acknowledges in his rejection. Sneider's container is used to protect handlers when mixing drug substances together and as a result is of limited relevance. The center portion of the container is connected to, and contains a rigid container constrained so as not to produce mixing of the contents before the desired time. No such device is contemplated in the instant invention.

In his rejection, the Examiner claims that "Sneider discloses a container having a planar wall, a radiused periphery, and a peripheral ledge which retains its shape." No proof that Sneider retains its shape is offered, and there is no indication of the particular shapes that characterize the container of the present invention in the disclosure of Sneider. Few details are given regarding the construction of Sneider's envelope-shaped

col. 3  
line 53

col. 4, ll 49-53

container, other than that it contains liquid without breaking or leaking. Sneider gives no details of the seamed edge, which are crucial to redirecting the phase change forces experienced by the container of the instant invention. The fact that a container contains liquid without rupture is not indicative of that container's physical behavior when subjected to extreme forces in non-ambient conditions. Thus, Sneider does not contain all of the elements of the present invention, nor does it provide the benefits thereof.

a) the device shows an edge  
b) Heck teaches that container constructed w/ vacuum molding machine have

The Examiner cites Heck for teaching that "medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves." It is respectfully submitted that this general statement of formation technique without regard to the ultimate use or operating environment of a container does not provide sufficient motivation to combine such a reference with any other. Even if this were a specific teaching that provided sufficient motivation for combination, a mere formation technique such as that cited here by the Examiner (blow molding or vacuum molding) would not cure the deficiencies of the Sneider patent with regard to the present invention.

The Examiner has also cited the patent to Nathoo, and undersigned respectfully submits that Nathoo has no relevance here. The Examiner states, "Nathoo evidences that vacuum molded halves are less susceptible to tearing" and cites Nathoo's abstract for this proposition.

This assertion suffers from the same problem as the Examiner's assertion with regard to Heck, discussed hereinabove. Here, the Examiner makes a general assertion about properties for formed items without evidence and without consideration of the details of the formation methods. Not all vacuum-molding methods produce suitable results for all applications.

Nathoo teaches laminate assembly utilizing elastomeric sheets that conform to the mold. Between each molding cycle, the molds separate, and the sheets remain in place, not conformed to the molds, but positioned between them. The molding technique uses fiber-based preform materials (col. 4, lines 42-46) that have nothing to do with the present invention. Even if the Examiner's assertions were appropriate, Nathoo is non-analogous art.

Moreover, it is the very unsuitable nature of conventional techniques discussed in Heck and Nathoo that has prompted the applicant to delve into the art. Applicant claims a method unlike that of the prior art.

ISSUE NUMBER 4:

**Whether claims 19-22, 56, 57, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al (USP 5,108, 387) in view of Heck (USP 4,428,743) with or without evidence by Nathoo (USP 4,943,222) or Medwed (USP 4,397,804):**

**Examiner's Position**

"Falk discloses a container having a planar wall, a radiused periphery and a peripheral ledge which retains its shape (fig. 1a). However, Sneider (sic) does not explicitly identify how the container is constructed. Heck teaches in an alternate medical container that medical containers can be constructed by a number of conventional ways including blow molding as well as vacuum molding individual halves (col. 2, lines 29-39). Nathoo evidences that vacuum molded halves are less susceptible to tearing (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the formation of the container of Falk because the prior art recognized that vacuum molding is a conventional means for constructing medical containers. In addition, it

would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Heck for the container of Sneider (sic) as evidenced by Nathoo because vacuum formed devices are less susceptible to tearing. Both Nathoo and Medwed evidence that vacuum molded halves contain peripheral flashings. Falk discloses a plurality of portals (5, 6) of which 5 is sealed after filling (col. 4, lines 10-28) and the teaching of Falk in view of Heck would result in the use of two molds each having the claimed shape. With respect to claim 60 (those limitations not covered above) a container having the set forth shape would inherently be resistant to forces engendered by medical fluid undergoing a phase change. Falk teaches utilizing the container for dialysis concentrates which can include thermolabile or biological substances such as enzymes or antibodies."

#### **Appellant's Position**

One might surmise Falk and Sneider are quite similar structures due to their interchangeability by the Examiner. However their stark differences speak to the Examiner's caprice. Undersigned takes exception to all of the Examiner's combinations of references because they appear to be based on perhaps the inadvertent but nonetheless improper use of hindsight. As the precedents above compel, this is tantamount to penalizing the inventor by using his own patent specification and claims against him in providing the basis for assembling the mosaic of elements the Examiner has proffered. Clearly there is no such teaching or motivation in the prior art instructing such a combination.

Undersigned has read these patents carefully and has failed to uncover the basis by which the Examiner has combined these references to support an obviousness type rejection. Stated alternatively, there is no teaching within these citations that would

warrant the combination of elements proposed by the Examiner and it is respectfully stipulated that applicant's structure would still not be obtained thereby. A specific teaching within one of the references suggesting the combination is required.

Falk is directed to a collapsible container that retains its shape as it is emptied while resting on a surface. The collapsible container negates the desire to have uniform thickness required by applicant's claims to assure uniform heat transfer. The changeable nature of the shape of Falk's container prevents uniformity in the sidewall area adjacent to the seam, which will necessarily adjust upon collapse. Thus, Falk does not provide the correct geometry to distribute the phase change forces, because of its inherently adjustable/collapsible nature. The planar surface provided in the instant invention helps maintain as little temperature gradient as possible when storing multiple such bags together. The geometrical properties of Falk's container are dependent on the surface upon which the container rests.

It is respectfully submitted that a container that collapses in this manner cannot maintain the construction in the present invention adapted to respond to phase change forces. Because Falk's container is designed to collapse, the container volume may not exhibit predictable behavior upon filling and freezing, and because there is no consideration of such behavior, Falk is not applicable to the instant invention.

With regard to the combination of Falk with Heck and Nathoo and/or Medwed, the deficiencies of the latter three patents are discussed above. The attributes of these patents similarly do not cure the problems of Falk.

Finally, with regard to the Examiner's assertion with regard to claim 60 and the abovementioned patents, the Examiner merely states that "a container having the set forth shape would inherently be resistant to forces engendered by medical fluid

undergoing a phase change.” Inherence seems to be a species of “quasi judicial notice” based on the Examiner’s unarticulated perceptions. This appears to be gratuitous speculation devoid of support in the prior art and a failure to attach weight to claim terms. Even if this statement were true, the cited patents do not disclose containers required by the claims of the present invention, and the rejection under 35 U.S.C. § 103 should be withdrawn.

ISSUE NUMBER 5:

**Whether claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sneider in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed:**

ISSUE NUMBER 6:

**Whether claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk in view of Heck and Rake et al (USP 6,251,098) with or without evidence by Nathoo or Medwed:**

**Examiner’s Position**

“The references above set forth all the limitations of these new claims (see rejection above for discussion of limitations not covered here), but none of Sneider, Falk, or Heck explicitly set forth the use of a thermosetting material for the method of construction. Rake sets forth in an alternate medical container that it is conventional in the art to utilize materials such as thermosetting materials for the construction of medical containers (col. 10, lines 21-33). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Rake for the method of either Sneider or Falk in view of the Heck, because thermosetting materials are readily available and have been identified as suitable materials for medical

container construction. The containers constructed by the above references would also read on the claim language drawn to the resistance to brittleness and deformation giving those claim terms their broadest reasonable interpretation.”

### **Appellant's Position**

Sneider, Heck, Nathoo, and Medwed have all been discussed infra, their deficiencies explored and are hereby incorporated herein.

Rake has been included because his text merely includes the statement that “medical device housing” can be formed using “injection molding of thermoplastic or thermoset polymers”.

Applicant is not involved here with device housings or injection molding. The fact the Examiner can find key words in patent text is legally irrelevant.

The present invention claims a method of making flexible medical bags designed to produce bags of a particular conformation. Not all formation methods would produce a bag suitable for handling phase change forces. As mentioned above, it is the unsuitability of the prior art that calls for a new solution with respect to techniques and apparatus concerning material actively undergoing phase changes.

## GROUPING OF CLAIMS

### SUPPLEMENTAL OBSERVATIONS

To the extent not particularized infra, the reasoning that each claim stands alone and is independently patentable includes the following:

1) The Examiner's combination of references is flawed not only as to the independent claims but also as to those dependent claims which further limit and define the inventor.

2) Applicant is not attempting to obtain pioneer patent protection on the first "ledge" or "portal" (eg cl 19); that is not the test for patentability. The combination of elements is new, and the benefits are unattainable in the prior art (as combined) without invention having taken place.

Similarly claim 20 depends from claim 19 and inter alia requires, containing within said bag thermolabile substances, unlike any and all prior art.

Claim 21 depends from claim 19 and inter alia requires, containing within said bag cellular biological substances, unlike any and all prior art.

Claim 22 depends from claim 19 and inter alia requires, forming a second mold having a mirror image of the first mold and forming the bag by registering the formed sheet from the first mold and formed sheet from the second mold together, unlike any and all prior art.

Claim 56 depends from claim 20 and inter alia requires, forming a portal in the mold and bag and sealing at the portal the thermolabile substances in the bag, unlike any and all prior art.

Claim 57 depends from claim 21 and inter alia requires, forming a portal in the mold and the bag and sealing at the portal the cellular biological substances within the bag, unlike any and all prior art.

Claim 58 and claim 59 depend respectively from claim 56 and 57 and inter alia subsequently freezing the bag whereby the radiused periphery of the bag dissipates forces due to freezing within the bag, unlike any and all prior art.

Claim 60 requires, inter alia forming a medical bag resistant to forces engendered by medical fluid undergoing a phase change within the bag, unlike any and all prior art.

Claim 61 depends from claim 60 and requires, inter alia forming at least one closeable portal in the bag, unlike any and all prior art.

Claim 62 depends from claim 61 and requires, inter alia filling the bag with a thermolabile biological fluid and freezing the fluid in the bag, unlike any and all prior art.

Claim 63 requires, inter alia causing a conformed sheet to retain a conformed shape being flexible without brittleness or resistance to deformation, unlike any and all prior art.

Claim 64 requires, inter alia forming a first mold having at least one portal-shaped recess whereby a portal formed by said portal-shaped recess passes into an interior of the bag causing a conformed sheet to retain a conformed shape being flexible without brittleness or resistance to deformation, unlike any and all prior art.

Claim 65 requires, inter alia a method for forming a medical bag forming a first mold having at least one portal-shaped recess which is flexible without brittleness or

resistance to deformation, whereby a portal formed by said portal-shaped recess passes into an interior of the bag, unlike any and all prior art.

Claim 66 requires, inter alia a method for forming a flexible, memory-retaining medical bag, forming a first mold having at least one portal-shaped recess whereby a portal formed by said portal-shaped recess passes into an interior of the bag, unlike any and all prior art.

Claim 67 requires, inter alia a method for forming a bag, conforming a sheet material to a first mold, having at least one portal-shaped recess whereby a portal formed by a portal-shaped recess passes into an interior of the bag, unlike any and all prior art.

### CONCLUSION

In view of the foregoing, it is respectfully requested that the Examiner's final rejection be vacated, the rejections tendered by the Examiner be reversed and this case be passed to issue. Such action is respectfully requested.

The inclusion of the article by Baxter is more powerful than any legal argument as to patentability based on legal precedent, motivation, hindsight, etc.

One of the largest medical companies in the world - one with, for all practical purposes, unlimited assets - cannot see what the Examiner sees. Somehow, six patents spanning the last 20 years resolves the problems that have eluded Baxter. There is no teaching in the six patents - only the teaching supplied by applicant. The question, then, is: why didn't Baxter cobble together these six patents as is obvious or anticipated?

### APPENDIX OF THE CLAIMS ON APPEAL

Claim 19 - A method for forming a bag, the steps including:

forming a first mold having at least one portal-shaped recess and a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface, whereby a portal formed by said portal-shaped recess passes into an interior of the bag,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold and retain its conformation, whereby a conformed sheet includes a recess that includes a planar surface, radiused periphery and peripheral ledge,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Claim 20 - The method of claim 19 including containing within said bag thermolabile substances.

Claim 21 - The method of claim 19 including containing within said bag cellular biological substances.

Claim 22 - The method of claim 19 wherein enclosing the bag is performed by forming a second mold having a mirror image of the first mold and placing a blank of sheet material over said second mold causing the blank to conform to the mold and forming the bag by registering the formed sheet from the first mold and formed sheet from the second mold together.

Claim 56 - The method of claim 20 further including forming a portal in the mold and bag and sealing at the portal the thermolabile substances in the bag.

Claim 57 - The method of claim 21 further including forming a portal in the mold and the bag and sealing at the portal the cellular biological substances within the bag.

Claim 58 - The method of claim 56 including subsequently freezing the bag whereby the radiused periphery of the bag dissipates forces due to freezing within the bag.

Claim 59 - The method of claim 57 including subsequently freezing the bag whereby the radiused periphery of the bag dissipates forces due to freezing within the bag.

Claim 60 - A method for forming a medical bag which is resistant to forces engendered by medical fluid undergoing a phase change within the bag, the steps including:

forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface,

placing a blank of sheet material over said mold, and causing the blank to conform to the mold and retain its conformation, including a planar surface, radiused periphery and peripheral ledge,

removing the conformed sheet from the mold, and

closing the recess formed in the sheet with another sheet parallel to the planar surface such that the radiused periphery dissipates forces during phase change.

Claim 61 - The method of claim 60 including forming at least one closeable portal in the bag.

Claim 62 - The method of claim 61 including filling the bag with a thermolabile biological fluid and freezing the fluid in the bag.

Claim 63 - A method for forming a bag, the steps including:

forming a first mold having a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface,

placing a blank of sheet material over said first mold and causing the blank to conform to the mold and retain its conformation, whereby a conformed sheet includes a recess that includes a planar surface, radiused periphery and peripheral ledge, the sheet material composed of a material having a shape memory, whereby a conformed sheet retains a conformed shape after a conformation occurs, the conformed shape being flexible without brittleness or resistance to deformation,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Claim 64 - A method for forming a bag, the steps including:

forming a first mold having at least one portal-shaped recess and a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface, whereby a portal formed by said portal-shaped recess passes into an interior of the bag,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold and retain its conformation, whereby a conformed sheet includes a recess that includes a planar surface, radiused periphery and peripheral ledge, the sheet material composed of a material having a shape memory, whereby a conformed sheet retains a conformed shape which includes a planar surface, radiused

periphery and peripheral ledge after a conformation occurs, the conformed shape being flexible without brittleness or resistance to deformation,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Claim 65 - A method for forming a medical bag from a material having a shape memory, the steps including:

forming a first mold having at least one portal-shaped recess and a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface, whereby a portal formed by said portal-shaped recess passes into an interior of the bag,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold and retain its conformation, whereby a conformed sheet includes a recess that includes a planar surface, radiused periphery and peripheral ledge, wherein the conformed sheet retains a conformed shape which includes a planar surface, radiused periphery and peripheral ledge after a conformation occurs, the conformed shape being flexible without brittleness or resistance to deformation,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Claim 66 - A method for forming a flexible, memory-retaining medical bag, the steps including:

forming a first mold having at least one portal-shaped recess and a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface, whereby a portal formed by said portal-shaped recess passes into an interior of the bag,

placing a blank of sheet material over said first mold, and causing the blank to conform to the mold and retain its conformation, whereby a conformed sheet includes a recess that includes a planar surface, radiused periphery and peripheral ledge, the sheet material including a shape memory, whereby a conformed sheet retains a conformed shape which includes a planar surface, radiused periphery and peripheral ledge after a conformation occurs, the conformed shape being flexible without brittleness or resistance to deformation,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet parallel to the planar surface.

Claim 67 - A method for forming a bag, the steps including:

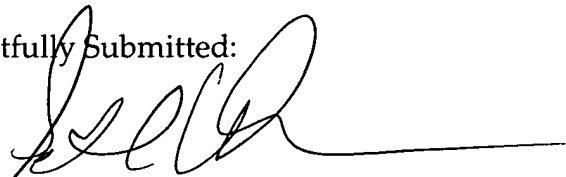
conforming a sheet material to a first mold, said first mold having at least one portal-shaped recess and a recess including a planar surface, a radiused periphery circumscribing said planar surface and a peripheral ledge circumscribing said radiused periphery and oriented parallel to said planar surface, whereby a portal formed by said portal-shaped recess passes into an interior of the bag, said material having a shape memory of a post-conformation shape,

removing the conformed sheet from the mold, and

closing the recess formed in the conformed sheet with another sheet  
parallel to the planar surface.

Dated: May 23, 2003

Respectfully Submitted:

A handwritten signature in black ink, appearing to read 'Bernhard Kreten', written over a horizontal line.

BERNHARD KRETEN  
Appellant's Attorney  
Telephone (916) 930-9700  
Registration No.: 27,037

Attach  
#16

**Baxter**

**EXHIBIT 1**

**URGENT  
PRODUCT  
INFORMATION**

March 3, 2003

**RE: Cryocyte Freezing Containers**

Dear Valued Customer,

The purpose of this communication is to provide you with some important information regarding our Cryocyte Freezing Containers.

Recently we have been investigating an increased incidence of container breakages observed by some customers.

Based on an analysis of product performance requirements for cryopreservation containers, we have concluded that the Cryocyte containers have not been providing consistent and reliable performance under the variety of conditions in which they are currently used. We have conducted numerous studies on these products and thus far we have been unable to identify a root cause of the breakage. As a result, we have decided to discontinue the sales and distribution of our Cryocyte product line effective June 30, 2003. We regret any inconvenience that this may cause you.

This Cryocyte product line includes the following product codes:

Product Code	Fill Volume	Container Size	Label Pocket	Pack Factor
R4R9951	10 - 20 mL	50 mL	Yes	24/case
4R9952	30 - 70 mL	250 mL	No	24/case
R4R9953	30 - 70 mL	250 mL	Yes	24/case
4R9954	55 - 100 mL	500 mL	No	24/case
R4R9955	55 - 100 mL	500 mL	Yes	24/case
4R9956	80 - 190 mL	750 mL	No	24/case
R4R9957	80 - 190 mL	750 mL	Yes	24/case
R4R9959	125 - 270 mL	1000 mL	Yes	24/case
R4R9960	Cryocyte Manifold Set			24/case

We will continue to provide you with the products you need through June 30<sup>th</sup>, 2003. You will need to make alternate arrangements for any cryopreservation container requirements you may have after that date. To obtain a list of alternate suppliers, please contact customer service at 1-800-888-2334, option 2. Please note that by providing this information Baxter is not endorsing the products offered by these suppliers. You should contact the alternate suppliers directly to determine if these products will meet your requirements.

Clinical investigators from the National Institutes of Health (NIH) have published their findings of tests conducted on cryogenic containers, which includes an overwrapping procedure that the NIH has used for the salvage of cells from broken or cracked containers (see *Cytherapy* (2002) Volume 4, Number 6, pages 539-549). Please be advised, however, that Baxter has not validated the NIH protocol and cannot confirm that it will meet your specific requirements. Attached you will find some reminders on the correct utilization of Cryocyte containers.

# ***Baxter***

We are committed to supporting you during this transition. If you have any questions regarding this notification, please contact your Baxter Oncology sales representative at 1-800-888-2334, option 4. Attached you will find a list of Frequently Asked Questions (FAQs) which may address some of your questions.

In order to confirm your receipt of this important information, please complete the attached reply form and fax it to 1+ (847) 270-5457. Thank you in advance for your cooperation.

Sincerely,



Al Volodka,  
Director, Quality Operations  
Baxter Healthcare Corporation

**Baxter**

Reply Record  
Cryocyte Freezing Containers  
(Letter dated March 3, 2003)

Please complete and return this record to FAX number (847) 270-5457

Subject: Urgent Product Information Regarding Cryocyte Freezing Containers

Facility Name and Address:

I have read and understand the information contained in the  
Cryocyte Freezing Container Urgent Product Information letter  
dated March 3, 2003.

Individual Completing Record  
(Please Print)

Title  
(Please Print)

Signature/Date

Phone Number

*Cryocyte is a trademark of Baxter International Inc.*

## **Cryocyte Frequently Asked Questions (FAQs) North American Customers**

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- 1. What is happening?**  
On March 3, 2003, Baxter's Product Surveillance Group sent an Urgent Product Information letter to all Baxter Oncology customers that have purchased Cryocyte Freezing Containers since 1999. The purpose of this communication was to provide our customers with important information regarding our Cryocyte Freezing Containers. The letter informed customers that recently we have been investigating an increased incidence of container breakages observed by some customers. Based on an analysis of product performance requirements for cryopreservation containers, we have concluded that the Cryocyte containers have not been providing consistent and reliable performance under the variety of conditions in which they are currently used. We have conducted numerous studies on these products and thus far we have been unable to identify a root cause of the breakage. As a result, we have decided to discontinue the sales and distribution of our Cryocyte product line effective June 30, 2003. We regret any inconvenience that this may cause you.
- 2. Do you know why there are performance issues with the Cryocyte products?**  
No. These products were manufactured to meet the design specifications and met the release requirements. Studies have been conducted on these products and we have been unable to identify a root cause of the breakage.
- 3. Why isn't Baxter striving to improve the Cryocyte products?**  
We have been unable to develop a predictive test that will allow us to ensure that we have eradicated the issues.
- 4. I currently have Cryocyte products in stock. Can I return them?**  
Please contact your customer service representative at 1-800-888-2334, option 2 for the Cryocyte product return policy.
- 5. Is there anything I can do to better ensure the integrity of the containers I currently have stored?**  
As a reminder, temperature transitions should be made as gradually as possible and bags should not be handled any more than usual. In order to maximize recovery of the contents stored in Cryocyte containers, you may wish to consider the applicability of findings published by the National Institutes of Health (NIH) on its study of cryogenic containers. The article (see *Cytotherapy* (2002) Volume 4, Number 6, pages 539-549) describes an overwrapping procedure that the NIH has used for the salvage of cells from broken or cracked Cryocyte containers. Please be advised, however, that Baxter has not validated this protocol, and cannot confirm that it will meet your specific requirements.
- 6. Who should I call if I have a product complaint?**  
Please contact Baxter Oncology Product Surveillance at 1-800-888-2334, option 3.
- 7. We have never had a problem with these bags. How much product can we purchase before June 30<sup>th</sup>?**  
We expect to be able to meet normal product demand through June 30, 2003. Please contact your Baxter Oncology sales representative at 1-800-888-2334, option 4 for any special concerns you may have.
- 8. If Baxter is no longer going to provide these products, where can I get comparable products?**  
A list of alternate suppliers is being made available to you via our customer service function at 1-800-888-2334, option 2. Please note that by providing this information Baxter is not endorsing the products offered by these suppliers. You will need to contact the suppliers directly to determine if these products will meet your requirements.

## Cryocyte Frequently Asked Questions (FAQs) – North American Customers

9. Are the alternate suppliers aware that you are exiting the market and are they equipped to meet the increased demand for product?

We will attempt to contact our competitors to help ensure a smooth transition.

10. I just purchased racking and storage systems to fit these bags. Will the alternate suppliers' bags fit into this system?

Please contact the manufacturer of your storage system for compatibility information.

11. Have there been any adverse patient incidents?

We have received reports of adverse patient incidents and have communicated these to the appropriate regulatory agencies.

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*Cryocyte is a trademark of Baxter International Inc.*



March 24, 2003

Dear Valued Customer,

As you know, we began notifying our customers on March 3, 2003, about two important actions we were taking regarding our Cryocyte Freezing Container product line. The first action was the issuance of an "Urgent Product Information" letter to all Cryocyte Freezing Container customers. That letter was prompted by an increase in the incidence of container breakages observed by a number of our customers. The March 3<sup>rd</sup> letter informed customers of the possibility of container breakage and advised customers to consider the use of an overwrap during thawing. That letter also provided a reminder as to the appropriate utilization of Cryocyte containers.

The second action was the decision announced in the March 3<sup>rd</sup> letter to discontinue the Cryocyte Freezing Container product line in June 2003. Since March 3<sup>rd</sup>, we have received feedback from a considerable number of our Cryocyte customers, either directly or through the International Society for Cellular Therapy (ISCT). Many of these customers expressed disappointment with our decision and have urged us to reconsider our position. Based upon this feedback, we have decided to reverse our decision and continue to provide the Cryocyte Freezing Container product line with the following understanding:

Due to the wide variability of uses among institutions, we cannot guarantee that there will not be container breakages in the future. Therefore, if you choose to continue using the Cryocyte container, we suggest that you validate your own procedures to ensure that the containers will meet your expectations when exposed to the processing conditions and practices employed in your institution. We would also suggest that you consider taking appropriate precautions, including the overwrapping procedure described by the National Institutes of Health (NIH) used for the salvage of cells from broken or cracked containers (see Cytotherapy (2002) Volume 4, Number 6, pages 539-549). Please be advised, however, that Baxter has not validated the NIH protocol and cannot confirm that it will meet your specific requirements.

As stated in the March 3<sup>rd</sup> letter, we have been unable to identify a root cause of the reported breakage, but we will continue our efforts. The International Society for Cellular Therapy has offered to assist us to further identify best-demonstrated methods and develop robust user guidelines. We will also continue to monitor ongoing product related feedback from customers.

We sincerely regret any inconvenience that this may have caused you and your institution, and we appreciate the considerable support that our many Cryocyte customers have expressed in recent weeks for this product line. We want to assure you that Baxter is committed to supporting our customers and continuing to meet your needs. Our sales force and technical specialists will be working closely with you over the next several weeks to provide additional information regarding this revised decision.

Thank you for your understanding and your support.

Sincerely,

A handwritten signature in cursive script that reads "Cynthia Collins".

Cynthia Collins  
President, Baxter Oncology

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## **Correct Utilization of Cryocyte Freezing Containers**

Some reminders on correct utilization of the Cryocyte container include:

- Do not overfill the bags. Filling guidelines for the bags are as follows:

CONTAINER SIZE	MAXIMUM FREEZING VOLUME
50 mL	20 mL
250 mL	70 mL
500 mL	100 mL
750 mL	190 mL
1000 mL	270 mL

- Remove as much air as possible before sealing and freezing.
- Be sure to double seal the port tubing.
- Make temperature transitions as gradual as possible (e.g., rate-controlled freezing).

In order to maximize recovery of frozen contents, you may wish to consider the use of an overwrap during the thawing process.



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**Typed Drawing**

**Word Mark** CRYOCYTE PACK

**Goods and Services** IC 010. US 044. G & S: DISPOSABLE PLASTIC BAG WITH OUTLET PORT AND CAP FOR COMPONENT FREEZING, STORING AND TRANSFUSION OF PLATELETS, PLASMA AND OTHER BLOOD PORTIONS. FIRST USE: 19700902. FIRST USE IN COMMERCE: 19700902

**Mark Drawing Code** (1) TYPED DRAWING

**Serial Number** 72371193

**Filing Date** September 21, 1970

**Registration Number** 0975998

**Registration Date** January 1, 1974

**Owner** (REGISTRANT) BAXTER LABORATORIES, INC. CORPORATION DELAWARE 6301 LINCOLN AVE. MORTON GROVE ILLINOIS 60053

(LAST LISTED OWNER) BAXTER INTERNATIONAL INC. CORPORATION BY CHANGE OF NAME FROM DELAWARE ONE BAXTER PARKWAY DEERFIELD ILLINOIS 60015

**Assignment Recorded** ASSIGNMENT RECORDED

**Disclaimer** APPLICANT DISCLAIMS "PACK" SEPARATE AND APART FROM THE MARK AS A WHOLE.

**Type of Mark** TRADEMARK

**Register** PRINCIPAL

**Affidavit Text** SECT 15. SECT 8 (6-YR).

**Renewal** 1ST RENEWAL 19940217

**Live/Dead Indicator** LIVE

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